DETAILED ACTION

Response to Arguments

1. Applicant argues that claim 5 was not rejected in the previous office action. After reviewing the office action the examiner noticed that claim 5 was rejected in the same manner as claim 17.

2. Applicant's arguments filed October 28, 2009 with respect to the drawings objections and the 112 rejection of claims 10-13, 15, 17, and 19-23 have been fully considered but they are not persuasive.

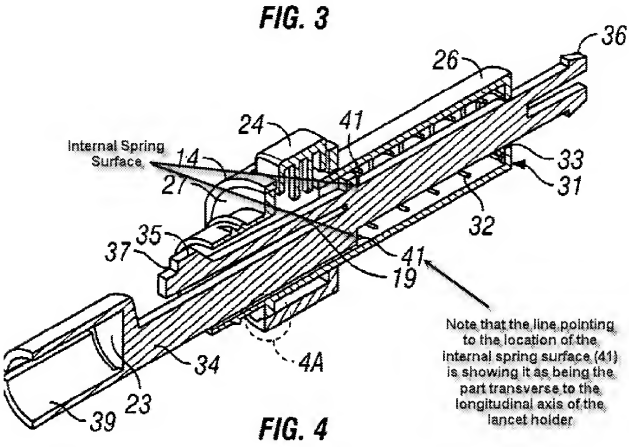
Applicant argues that the specification and drawings as originally disclosed do show that the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring.

The examiner disagrees with applicant's arguments since the original disclosure only mentions the one or more spring surfaces (41) in page 9 lines 5-7 where it states "one or more internal spring surfaces 41 against which the internal spring 32 can act to propel the lancet 20" and in Fig. 4.

Applicant refers to Fig. 4 and Fig. 5 to demonstrate that there is support for the limitation (see page 16 and 17 of arguments) however it seems to the examiner that the internal spring surface is on the surface transverse to the longitudinal axis of the lancet holder (see figure below) which would cause the spring force to propel the lancet as disclosed in the specification.

Applicant is incorrect on stating that the internal spring surface is throughout the length of the lancet holder as seen in page 16 and 17 of the arguments. Note that there is no

suggestion on the original disclosure that asserts applicants arguments; therefore the rejection and objection to drawings is maintained.



3. Applicant's arguments, with respect to the prior art rejection in view of Morita have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation based on the amendment to the claims.

4. Applicant's arguments, with respect to the rejection in view of the Hofert reference have been fully considered and are persuasive. The rejection has been

withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the reference.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation found in claim 10 and 13 that the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Note that applicant referred to Fig. 5 and indicated that the external spring (44) was engaging the one or more spring surfaces (41) (See page 22 of arguments). On the contrary, Fig. 5 shows the external spring (44) engaging the one or more retaining features (36) not the one or more spring surfaces.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claim 3 is objected to because of the following informalities: in the last line "equal; and" should be –equal.--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-13, 15, 17, 19-23, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 13 recite "the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring." This statement has no support in the original disclosure. The original disclosure does state that the internal spring (32) is engaged to the one or more spring surfaces (41), however the external spring is not disclosed as being engaged by the one or more spring surfaces (41).

Note that applicant referred to Fig. 5 and indicated that the external spring (44) was engaging the one or more spring surfaces (41) (See page 22 of arguments). On the contrary, Fig. 5 shows the external spring (44) engaging the one or more retaining features (36) not the one or more spring surfaces.

Since the limitation was not found in the written disclosure and the original drawings are not specifically showing the external spring engaged to the one or more spring surface, this statement is considered new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 and 39 claim a sloped collar ramp and a cantilevered detent, it is unclear if applicant refers to another sloped ramp and detent or if the detent is cantilevered.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 3, 5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Abulhaj et al. (6,852,119).

Claim 1: Morita discloses an adjustable nozzle assembly (1) through which a lancet can be propelled by a lancing device into a lancing surface, the adjustable nozzle assembly (1) comprising: an interior nozzle (3 specifically the top part 11) comprising a ramped groove (47) and a lancet wall (13); a collar (5) comprising a collar pin (53) that engages the ramped groove (47) and slides relative to the ramped groove (Col. 12 Lines 65-68 and Col. 13 Lines 9-14), the collar (5) being adapted to rotate relative to the interior nozzle (3,11) (Col. 12 Lines 12-15); and an exterior nozzle (7) comprising a contact surface (35) that extends beyond the lancet wall (13) of the interior nozzle (3,11) to contact the lancing surface (Fig. 1), the exterior nozzle (7) engaging the collar (5) (Col. 13 Lines 50-53) and being adapted to rotate relative to the interior nozzle (3,11) (Col. 13 Lines 58-60); and wherein the ramped groove (47) is sloped (Fig. 1) such that as the exterior nozzle (7) rotates relative to the interior nozzle (3, 11), the distance that the contact surface (35) extends beyond the lancet wall (13) changes by an amount that corresponds to the slope of the ramped groove (Col. 14 Lines 1-9).

Furthermore, Morita discloses an assembly groove (the distal end of the groove 47 which is straight in one portion), and that the collar pin (53) is configured to slide through the assembly groove to the ramped groove. The collar pin first slides to the distal end of the groove which is the assembly groove and then slides down to where the groove is ramped which is the ramped groove as seen in Fig. 1-2.

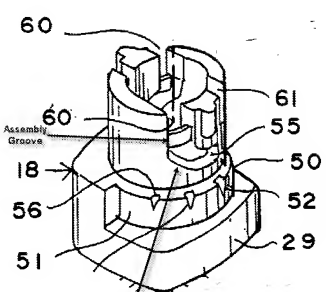
Morita further discloses a sloped mating ramp (37 where the sloped portion is the ramp leading from the notch (39) to the step (37) as best seen in Fig. 1) comprising a plurality of adjustment notches (39) (Col. 12 Lines 1-2); collar (5) further comprises a

sloped collar ramp (the ramp in portion 51 and 57) with a detent (57) on one end (Fig. 2), wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation (Col. 12 Lines 1-9).

Morita discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the notches on the interior nozzle and the recess on the collar, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Morita discloses all the claimed limitations discussed above however, Morita does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.

Abulhaj discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism (Fig. 15-16 where the pin (31) enters the groove seen in the figure below) where the groove has an assembly groove (see figure below) extending in a first direction (it extends longitudinally from the proximal end towards the distal end) and a ramped groove (see figure below) extending in a second direction (it extends diagonally as seen in the figure below) deviating from the first direction (see figure below).



The substitution of one known element (the ramped and assembly groove of the threaded mechanism of Morita) for another (the ramped and assembly groove of the pin/groove mechanism of Abulhaj) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of two well known connection mechanisms (pin/groove and threaded) which are used as depth mechanism such as the one shown in Abulhaj would have yielded predictable results of an adjustable depth mechanism.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita with the pin/groove mechanism that contains an assembly groove extending in a direction which is deviated form the direction of the ramped groove, in order to have an entry point for the pin which would allow the pin to slid straight through until the ramped groove is reached.

Claim 3: Morita in view of Abulhaj discloses the claimed invention except for the slope of the collar ramp and the slope of the mating ramp being approximately equal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the slopes approximately equal, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 5: Morita discloses that the detent forms a slotted portion of the collar ramp (Fig. 2).

Claim 7: Morita discloses that the collar (5) further comprises one or more collar alignment features (29, 25), and the exterior nozzle (7) further comprises one or more exterior nozzle alignment features (65, 55) that can engage the one or more collar alignment features (Col. 13 Lines 45-49 and Col. 14 Lines 28-30).

Claim 9: Morita discloses that the ramped groove (47) comprises an over-rotation groove. The ramped groove (47) has ends which are thinner which would not allow the collar (5) to rotate more than that point. Furthermore, the interior nozzle has a stopper (43) which will stop the device one component (25) of the collar (5) hit it. This is a prevention to over-rotation in addition to the end of the groove (47).

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Abulhaj et al. (6,852,119) and further in view of Duchon et al. (5,964,718).

Morita in view of Abulhaj discloses all the claimed limitations discussed above however, Morita in view of Abulhaj does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita in view of Abulhaj with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

14. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446).

Hofert discloses the following claim limitations:

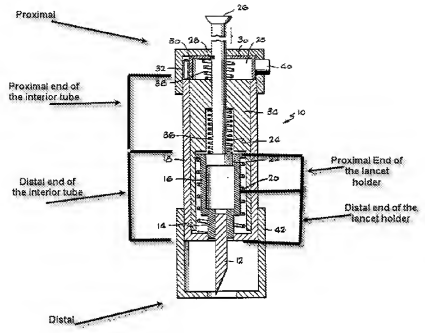
Claim 10: A rearward body assembly of a lancing device that can propel a lancet (12) into a lancing surface, the rearward body assembly comprising: a lancet holder (16) comprising one or more retaining features (14) and one or more spring surfaces (the outer area and the top surfaces of the lancet holder are spring surfaces since the surface is in contact with the springs) at the distal end (see figure below where the distal end is labeled) and one or more lancet holding features (the internal wall of 14 and 16 as seen in the Figure) at the proximal end (the proximal portion of the holding features is at the proximal end as defined in the figure below); an interior tube (34) comprising an open end (proximal end as seen in the Figure) and a slotted end (distal end where it is stepped and has an opening as seen in the Figure) through which the one or more

retaining features extend (see the Figure where it extends out when the lancet holder is propelled out), the interior tube (34) being adapted to slidably engage the lancet holder (16) (the lancet holder is placed inside the inner tube as seen in the Figure); a finger cover (18) (note that the finger cover according to applicant's drawings is a collar that goes over the interior tube as best seen in Fig. 3 of the current application) arranged along a periphery of the interior tube (see Figure); an internal compression spring (36) comprising a first end and a second end (see Figure), the first end of the internal compression spring (36) being adapted to act on the slotted end of the interior tube (34) (the proximal end of the spring is in contact with the slotted area as seen in the Figure) and the second end of the internal compression spring (36) being adapted to act on the one or more spring surfaces of the lancet holder (16) (the distal end is in contact with the lancet holder so when a force is applied on the spring it will act on the spring surfaces); a retainer (42) comprising a slotted surface (opening where the finger collar enters) at the distal end of the interior tube (see figure below) through which the one or more retaining features extend (see the Figure where it extends out when the lancet holder is propelled out); a rearward body (combination of 24 and 22), the rearward body engaging the retainer (it is indirectly engaged to the retainer); wherein longitudinal movement of the rearward body away from the interior tube compresses the interior compression spring (36) (by pulling on the rearward body it can compress the interior tube) (Col. 3 Lines 5-10) and an external compression spring (20) comprising a first end and a second end (see the Figure), the first end comprising a reduced coil diameter that engages the one or more retaining features (14) of the lancet holder (16) as seen in the

Figure, the first end of the external compression spring being adapted to act on the lancet holder (the spring is holding the lancet holder which will act on it to cause the deployment of the lancet) and the second end of the external compression spring being adapted to act on the slotted surface of the retainer (the spring is compressing on the retainer therefore it is acting on the slotted surface); and wherein the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring (see Figure where the one or more spring surfaces engages indirectly to both spring).

Regarding the "adapted to" statements, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Hofert discloses the claimed invention including that the rearward body is positioned externally of the interior tube (a portion of the rearward body is external as well as when it is pulled it will be external). However Hofert does not disclose that the rearward body is positioned around the periphery of the interior tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make that handle (26) of the rearward body be around the periphery of the interior tube in order to simplify the device and since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.



Claim 11: That the lancet holder (16) further comprises a trigger extension (22), the trigger extension being adapted to engage both a trigger and the interior tube to load the lancing device and to oppose the force of the compression spring until the trigger is actuated. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim 12: That the retainer further comprises one or more retainer alignment features (interior wall of the retainer which attaches to the finger cover), and the rearward body further comprises one or more rearward body alignment features (the piece 24 serves as an alignment feature which has to fit on the center of the lancet holder (16) which has the retainer (14)) that can engage the one or more retainer alignment features. The

rearward body engages to the step portions of the retainer which maintains the rearward body centered.

15. Claims 13, 15, 19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and further in view of Abulhaj et al. (6,852,119).

Hofert teaches all the claimed limitations discussed above (see rejections of claims 10-12 which reads on the rearward assembly of claims 13, 22, and 23) however, Hofert does not disclose an adjustable nozzle assembly.

Morita discloses all the features of the adjustable nozzle claimed in claims 15, 17, 19, and 21 (refer to rejections of claims 1, 3, 5, 7, and 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert with an adjustable nozzle in view of the teachings of Morita, in order to adjust the puncturing depth of the lancet on the tissue which will adapt to different skin thickness or change the amount of blood that needs to be collected.

Hofert in view of Morita discloses all the claimed limitations discussed above however, Hofert in view of Morita does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.

Abulhaj discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism (Fig. 15-16 where the pin (31) enters the groove seen in the figure above in the rejection of claim 1) where the groove has an

assembly groove (see figure above in the rejection of claim 1) extending in a first direction (it extends longitudinally from the proximal end towards the distal end) and a ramped groove (see figure above in the rejection of claim 1) extending in a second direction (it extends diagonally as seen in the figure above in the rejection of claim 1) deviating from the first direction (see figure above in the rejection of claim 1).

The substitution of one known element (the ramped and assembly groove of the threaded mechanism of Morita) for another (the ramped and assembly groove of the pin/groove mechanism of Abulhaj) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of two well known connection mechanisms (pin/groove and threaded) which are used as depth mechanism such as the one shown in Abulhaj would have yielded predictable results of an adjustable depth mechanism.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita with the pin/groove mechanism that contains an assembly groove extending in a direction which is deviated form the direction of the ramped groove, in order to have an entry point for the pin which would allow the pin to slid straight through until the ramped groove is reached.

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and Abulhaj et al. (6,852,119) and further in view of Duchon et al. (5,964,718).

Hofert in view of Morita and Abulhaj discloses all the claimed limitations discussed above however, Hofert in view of Morita and Abulhaj does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita and Abulhaj with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
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